Attachment 5

NOV - 4 2011

510(k) Summary of Safety and Effectiveness for the

Dimension Vista® Lithium (LITH) Flex® Reagent Cartridge

Dimension Vista® Drug 4 Calibrator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: k112142

B. Date of Preparation: July 25, 2011

C. Proprietary and Established Names:

Dimension Vista® Lithium (LITH) Flex® Reagent Cartridge (K4150)

Dimension Vista® Drug 4 Calibrator, DRUG 4 CAL (KC460A)

D. Applicant:

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101, Newark, DE 19714-6101

Rose Marinelli, Regulatory Technical Specialist

Office Number: (302) 631-8805; Fax Number: (302) 631-6299

E. Regulatory Information:

Lithium (LITH) Flex® Reagent Cartridge:

1. Regulation section: 21 CFR § 862.3560 Lithium test system
2. Classification: Class II
3. Product Code: NDW
4. Panel: Clinical Toxicology Test Systems

Drug 4 Calibrator:

1. Regulation section: 21 CFR § 862.1150 Calibrator
2. Classification: Class II
3. Product Code: JIX – Calibrator, Multi-Analyte Mixture
4. Panel: Clinical Chemistry Test Systems

F. Predicate Device:

The predicate device used to demonstrate substantial equivalence to the Dimension Vista® Lithium (LITH) Flex® Reagent Cartridge is the Dimension® Lithium (LI) Flex® Reagent Cartridge previously cleared under K011033.

The predicate device used to demonstrate substantial equivalence to the Dimension Vista® Drug 4 Calibrator is the current commercial Dimension® Drug Calibrator previously cleared under k011035.

G. Device Description: The LITH method employs a lithium-specific chromoionophore that forms a complex with the Li+ ion in an alkaline solution.

Li+ + Lithium Dye → Dye – Li Complex (absorbs at 510 nm)

The concentration of lithium in the sample is proportional to the increase in absorbance, which is due to the formation of the dye-lithium complex. The reaction is measured using a Bichromatic (510 and 700 nm) endpoint technique.

The Drug 4 Calibrator is a five (5) level, liquid calibrator. It is packaged as a kit of ten vials, two vials per level (A, B, C, D and E), 2.5 mL per vial. The product matrix is liquid human serum and contains digoxin and lithium. This product is sold separately from the Flex® reagent cartridge.

H. Intended Use: The LITH method is an *in vitro* diagnostic test for the quantitative measurement of lithium in human serum and plasma on the Dimension Vista® System. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

The Drug 4 CAL is an *in vitro* diagnostic product for the calibration of the LOCI Digoxin (DIGXN) and Lithium (LITH) methods on the Dimension Vista® System.

I. Substantial Equivalence Information:

The Dimension Vista® Lithium Flex® reagent cartridge, (LITH) K4150 and Dimension Vista® Drug 4 Calibrator (DRUG 4 CAL), KC460A were compared to the respective predicate devices, Dimension Lithium, (LI) DF132, cleared under k011033 and Dimension® Drug Calibrator (DRUG CAL) DC22B, cleared under k011035. A comparison of the similarities and differences between the devices is provided in the following tables:

Attachment 5

Feature	Dimension Vista® Lithium (LITH) K4150	Predicate: Dimension® Lithium (LI) k011033 – DF132
Intended Use	The LITH method is an *in vitro* diagnostic test for the quantitative measurement of lithium in human serum and plasma on the Dimension Vista® System. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).	The LI method used on the Dimension® clinical chemistry systems is an *in vitro* diagnostic test intended to quantitatively measure lithium in human serum and plasma (sodium heparin). Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).
Sample Type	Serum and Sodium Heparin Plasma	Serum and Sodium Heparin Plasma
Measuring Range	0.20 – 3.00 mmol/L	0.20 – 5.00 mmol/L
Sample Size	2 µL	10 µL
Measurement	Bichromatic endpoint (510 and 700 nm)	Bichromatic endpoint (540 and 700 nm)

Feature	Dimension Vista® DRUG 4 CAL (KC460A)	Predicate: Dimension® DRUG CAL (DC22B) k011035
Intended Use	The Drug 4 CAL is an *in vitro* diagnostic product for the calibration of the LOCI Digoxin (DIGXN) and Lithium (LITH) methods on the Dimension Vista® System.	The Drug 1 CAL is an *in vitro* diagnostic product for the calibration of the Digoxin (DIG), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN) and Theophylline (THEO) methods on the Dimension Vista® System.
Matrix	Human serum based	Human serum based
Preparation	Liquid: Provided ready to use.	Liquid: Provided ready to use.
Target Concentrations	Level 1 (CAL A): ≤ 0.20 mmol/L Level 2 (CAL B): 0.77 – 1.15 mmol/L Level 3 (CAL C): 1.67 – 2.00 mmol/L Level 4 (CAL D): 3.35 – 3.85 mmol/L Level 5 (CAL E): 5.12 – 5.89 mmol/L	Level 1: ≤ 0.20 mmol/L Level 2: 0.80 – 1.00 mmol/L Level 3: 1.71 – 1.89 mmol/L Level 4: 3.42 – 3.78 mmol/L Level 5: 5.22 – 5.78 mmol/L
Storage	Store at 2 - 8 °C.	Store at 2 to 8 °C.

J. Conclusion:

The Lithium (LITH) Flex® reagent cartridge is substantially equivalent to the Dimension® Lithium (LI) (k011033). The Dimension Vista® Drug 4 Calibrator (DRUG 4 CAL) is substantially equivalent to the Dimension® Drug Calibrator (DRUG CAL) (k011035). Comparative testing described in the submission report demonstrates substantial equivalent performance.

Attachment 5

510(k) Summary of Safety and Effectiveness for the

Dimension Vista® Lithium (LITH) Flex® Reagent Cartridge

Dimension Vista® Drug 4 Calibrator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: k112142

B. Date of Preparation: July 25, 2011

C. Proprietary and Established Names:

Dimension Vista® Lithium (LITH) Flex® Reagent Cartridge (K4150)

Dimension Vista® Drug 4 Calibrator, DRUG 4 CAL (KC460A)

D. Applicant:

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101, Newark, DE 19714-6101

Rose Marinelli, Regulatory Technical Specialist

Office Number: (302) 631-8805; Fax Number: (302) 631-6299

E. Regulatory Information:

Lithium (LITH) Flex® Reagent Cartridge:

1. Regulation section: 21 CFR § 862.3560 Lithium test system
2. Classification: Class II
3. Product Code: NDW
4. Panel: Clinical Toxicology Test Systems

Drug 4 Calibrator:

1. Regulation section: 21 CFR § 862.1150 Calibrator
2. Classification: Class II
3. Product Code: JIX – Calibrator, Multi-Analyte Mixture
4. Panel: Clinical Chemistry Test Systems

F. Predicate Device:

The predicate device used to demonstrate substantial equivalence to the Dimension Vista® Lithium (LITH) Flex® Reagent Cartridge is the Dimension® Lithium (LI) Flex® Reagent Cartridge previously cleared under K011033.

The predicate device used to demonstrate substantial equivalence to the Dimension Vista® Drug 4 Calibrator is the current commercial Dimension® Drug Calibrator previously cleared under k011035.

G. Device Description: The LITH method employs a lithium-specific chromoionophore that forms a complex with the Li+ ion in an alkaline solution.

Li+ + Lithium Dye → Dye – Li Complex (absorbs at 510 nm)

The concentration of lithium in the sample is proportional to the increase in absorbance, which is due to the formation of the dye-lithium complex. The reaction is measured using a Bichromatic (510 and 700 nm) endpoint technique.

The Drug 4 Calibrator is a five (5) level, liquid calibrator. It is packaged as a kit of ten vials, two vials per level (A, B, C, D and E), 2.5 mL per vial. The product matrix is liquid human serum and contains digoxin and lithium. This product is sold separately from the Flex® reagent cartridge.

H. Intended Use: The LITH method is an *in vitro* diagnostic test for the quantitative measurement of lithium in human serum and plasma on the Dimension Vista® System. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

The Drug 4 CAL is an *in vitro* diagnostic product for the calibration of the LOCI Digoxin (DIGXN) and Lithium (LITH) methods on the Dimension Vista® System.

I. Substantial Equivalence Information:

The Dimension Vista® Lithium Flex® reagent cartridge, (LITH) K4150 and Dimension Vista® Drug 4 Calibrator (DRUG 4 CAL), KC460A were compared to the respective predicate devices, Dimension Lithium, (LI) DF132, cleared under k011033 and Dimension® Drug Calibrator (DRUG CAL) DC22B, cleared under k011035. A comparison of the similarities and differences between the devices is provided in the following tables:

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Feature	Dimension Vista® Lithium (LITH) K4150	Predicate: Dimension® Lithium (LI) k011033 – DF132
Intended Use	The LITH method is an *in vitro* diagnostic test for the quantitative measurement of lithium in human serum and plasma on the Dimension Vista® System. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).	The LI method used on the Dimension® clinical chemistry systems is an *in vitro* diagnostic test intended to quantitatively measure lithium in human serum and plasma (sodium heparin). Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).
Sample Type	Serum and Sodium Heparin Plasma	Serum and Sodium Heparin Plasma
Measuring Range	0.20 – 3.00 mmol/L	0.20 – 5.00 mmol/L
Sample Size	2 µL	10 µL
Measurement	Bichromatic endpoint (510 and 700 nm)	Bichromatic endpoint (540 and 700 nm)

Feature	Dimension Vista® DRUG 4 CAL (KC460A)	Predicate: Dimension® DRUG CAL (DC22B) k011035
Intended Use	The Drug 4 CAL is an *in vitro* diagnostic product for the calibration of the LOCI Digoxin (DIGXN) and Lithium (LITH) methods on the Dimension Vista® System.	The Drug 1 CAL is an *in vitro* diagnostic product for the calibration of the Digoxin (DIG), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN) and Theophylline (THEO) methods on the Dimension Vista® System.
Matrix	Human serum based	Human serum based
Preparation	Liquid: Provided ready to use.	Liquid: Provided ready to use.
Target Concentrations	Level 1 (CAL A): ≤ 0.20 mmol/L Level 2 (CAL B): 0.77 – 1.15 mmol/L Level 3 (CAL C): 1.67 – 2.00 mmol/L Level 4 (CAL D): 3.35 – 3.85 mmol/L Level 5 (CAL E): 5.12 – 5.89 mmol/L	Level 1: ≤ 0.20 mmol/L Level 2: 0.80 – 1.00 mmol/L Level 3: 1.71 – 1.89 mmol/L Level 4: 3.42 – 3.78 mmol/L Level 5: 5.22 – 5.78 mmol/L
Storage	Store at 2 - 8 °C.	Store at 2 to 8 °C.

J. Conclusion:

The Lithium (LITH) Flex® reagent cartridge is substantially equivalent to the Dimension® Lithium (LI) (k011033). The Dimension Vista® Drug 4 Calibrator (DRUG 4 CAL) is substantially equivalent to the Dimension® Drug Calibrator (DRUG CAL) (k011035). Comparative testing described in the submission report demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 04 2011

Siemens Healthcare Diagnostics
c/o Rose T. Marinelli
P.O. Box 6101
Newark, DE 19714

Re: k112142
Trade/Device Name: Dimension Vista® Lithium (LITH) Flex® Reagent Cartridge, Dimension Vista® Drug 4 Calibrator
Regulation Number: 21 CFR 862.3560
Regulation Name: Lithium test system
Regulatory Class: II
Product Code: NDW, JIX
Dated: October 4, 2011
Received: October 5, 2011

Dear Ms. Marinelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k112142

Device Name: Dimension Vista® Lithium Flex® reagent cartridge, (LITH) K4150

Indications for Use: The LITH method is an *in vitro* diagnostic test for the quantitative measurement of lithium in human serum and plasma on the Dimension Vista® System. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

Device Name: Dimension Vista® Drug 4 Calibrator, (DRUG 4 CAL) KC460A

Indications for Use: The Drug 4 Calibrator is an *in vitro* diagnostic product for the calibration of the LOCI Digoxin (DIGXN) and Lithium (LITH) methods on the Dimension Vista® System.

Prescription Use √

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 112142